## 510(k) Summary of Safety and Effectiveness
## Jet-X® TiN Coated Half Pins

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| **Submitted By:** | Smith & Nephew, Inc.<br>Orthopaedic Division<br>1450 Brooks Road<br>Memphis, TN 38116 |
| **Date:** | September 19, 2002 |
| **Contact Person:** | David Henley<br>Senior Clinical/Regulatory Affairs Specialist<br>Tel: (901) 399-6487<br>Fax: (901) 398-5146 |
| **Proprietary Name:** | **Jet-X TiN Coated Half Pins-** |
| **Common Name:** | Half Pins |
| **Classification Name and Reference:** | Smooth or threaded metallic bone fixation fastener, 21CFR888. 3040, Class II |
| **Device Product Code and Panel Code:** | Orthopedics/87 |

OCT 0 9 2002

**Device Description:**
The Jet-X TiN Coated Half Pin is a modification of the Hex-Fix Half Pin that was cleared for market under K953397. This submission provides for a titanium nitride (TiN) coated stainless steel half pin.

**Intended Use:**
The Jet-X TiN Coated Half Pin is intended to be used with an external fixation system for fracture fixation (open and closed); pseudoarthrosis or nonunion of long bones; limb lengthening by epiphyseal or metaphyseal distraction, correction of bony or soft tissue deformity; correction of segmental bony or soft tissue defects; and joint arthrodesis.

**Technological Characteristics:**
The principles of operation for the Jet-X TiN Coated Half Pin are identical to the Hex-Fix Half Pin and the Richards Titanium Half Pin. Both are half pins that are used with external fixation systems for fracture fixation (open and closed) and other indications listed above. The titanium nitride (TiN) coating is a similar coating currently used on the B-P Extended Collar Femoral Stem Prostheses marketed by Endotec, Inc. and on the Sherlock Threaded Suture Anchor marketed by Doctor's Research Group, Inc. The design and material of the Jet-X TiN Coated Half Pin has the same technological characteristics as one or more of the predicate devices.

**Substantial Equivalence Information:**
The intended use of the Jet-X TiN Coated Half Pin is identical to the half pin predicate devices. The Jet-X TiN Coated Half Pin shape and design are identical to the Hex-Fix and Richards Half Pin predicate devices. The device is manufactured from the identical material, 316L stainless steel, as the Hex-Fix Half Pin. The titanium nitride (TiN) coating is a similar coating used on the B-P Acetabular Component System and Sherlock Threaded Suture Anchor predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 9 2002

Mr. David Henley
Senior Clinical/Regulatory Affairs Specialist
Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, Tennessee 38116

Re: K023134
Trade/Device Name: Jet-X™ TiN Coated Half Pins
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: JDW
Dated: September 19, 2002
Received: September 20, 2002

Dear Mr. Henley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

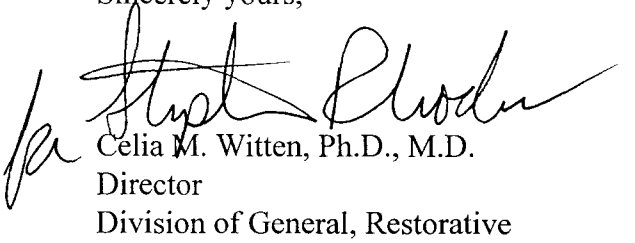
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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# Indications for Use Statement

**Jet-X® TiN Coated Half Pin**

510(k) Number (if known): K023134

Device Name: **Jet-X TiN Coated Half Pin**

Indications for Use:

The Jet-X TiN Coated Half Pin is intended to be used with an external fixation system for fracture fixation (open and closed); pseudoarthrosis or nonunion of long bones; limb lengthening by epiphyseal or metaphyseal distraction, correction of bony or soft tissue deformity; correction of segmental bony or soft tissue defects; and joint arthrodesis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The Counter Use_____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023134